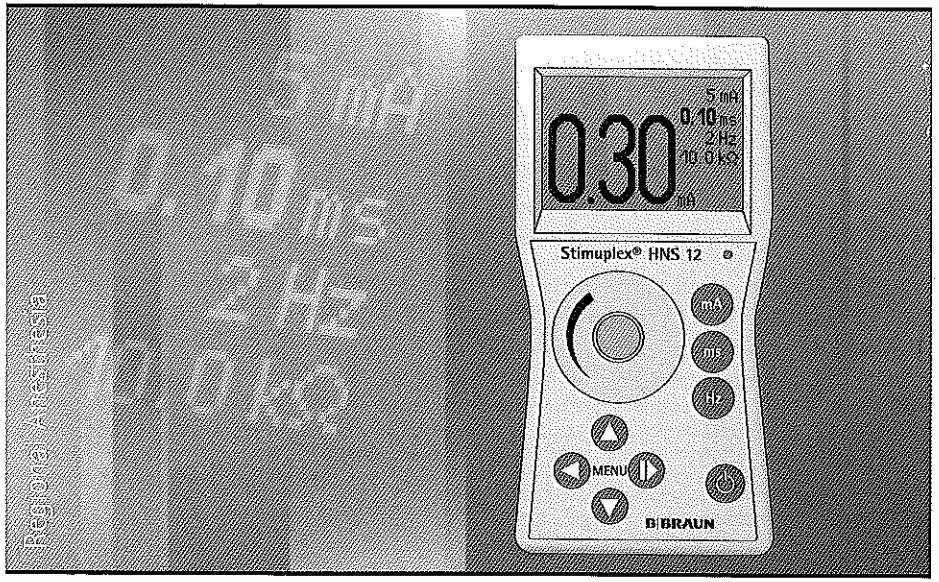
Stimuplex® HNS 12

Nerve Stimulator for
Peripheral Regional Anesthesia



Technical Service Manual

B|BRAUN

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Caution:
The Stimuplex® HNS 12 may only used in applications for which this product is intended. Federal (US) law restricts this device to sale by or on the order of a physician.

Stimuplex® HNS 12 Technical Service Manual
Order number: 604 3572 – Rev. A – valid for software version 1.002.x

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The **Stimuplex® HNS 12** is a nerve stimulator used for locating peripheral nerves in regional anesthesia and pain therapy.

The **Stimuplex® HNS 12** is a class IIa medical device according to Council Directive 93/42/EEC.

The device may not be put into operation until the supplier has subjected the device to an on-site function test (appropriate test instructions see page 9) and has instructed the persons responsible for operating the device about the device's handling with the aid of the user manual.

Type:	Stimuplex® HNS 12
Instrument type:	BF
Battery:	9 V (alkaline)
Power consumption:	6 mA (8 mA maximum)
Stimulation current:	$\hat{I}$ = 5 mA (maximum) (0-12 kΩ)
Stimulation voltage:	$\hat{U}$ = 95 V (maximum)
Stimulation frequency:	1 Hz / 2 Hz +/- 1%
Stimulus duration:	0.05 ms – 0.10 ms – 0.30 ms – 0.50 ms – 1.00 ms +/- 1%
Allowable load impedance:	0 kΩ – 12 kΩ
Current measuring accuracy:	+/- 0.02 mA
Impedance measuring range:	1 kΩ – 90 kΩ for target stimulation current > 0.5 mA
Impedance measuring accuracy:	+/- 10 % for stimulation current > 1 mA +/- 20 % for stimulation current <= 1 mA
Sound pressure level:	51 dB / 54 dB / 63 dB for stimulation/warning/ error
Weight:	250 g
Ambient conditions during operation:	0 – 50 °C, maximum 90 % relative humidity, no condensation

1.1 Battery

The battery charge status must be checked regularly (MENU info = state of charge indicated in "percent" and "volt"). Whenever the battery symbol is flashing, the current application can be completed without problems, but the battery should be replaced afterwards.

Please do not replace the battery when the device is switched on. This may damage the LCD display.

If the voltage is less than 6.00 V, an error message will be displayed and the device will switch off automatically. Replace battery.

If the Stimuplex® HNS 12 nerve stimulator is not intended to be used for a long period of time, the battery must be removed to prevent leakage.

The battery compartment is located in the base of the nerve stimulator. When installing the battery, ensure correct polarity and that the battery contacts are not pressed too tightly together to ensure solid contact.

Only use **9 V alkaline manganese batteries** – e.g. VARTA 4922, DURACELL MN 1604.
These will provide you with an optimum operating time.

WARNING!

If the battery is leaking, Stimuplex® HNS 12 should no longer be operated for reasons of safety. It must be returned to the manufacturer for correct cleaning and a safety check.

1.2 Cleaning and disinfecting Stimuplex® HNS 12

Use only soft, damp cloths to clean and disinfect Stimuplex® HNS 12 and electrode cables. Water and soap are especially suited for this purpose. Ensure that no moisture penetrates Stimuplex® HNS 12. **Use only wipe disinfection, no spray disinfection! Avoid condensation!**
For disinfection, you can use Meliseptol®.

We recommend running the following simple checks before starting up operation for the first time and then regularly (e.g. before daily use):

- Visual inspection of device and accessories
- Functional check of device

2.1 Visual inspection of Stimuplex® HNS 12 including accessories

The following components must be clean and undamaged and not show any contamination:

- Housing
- Labels
- Operating controls (instant set keys)
- Keypad
- LCD display
- Controller dial (digital control knob)
- Connecting ports
- Electrode cable (e.g. insulation or electrodes not broken)
- Test resistor

If included:

- Stimuplex® Remote Control
- Stimuplex® Pen

Never use damaged equipment or accessories!

After visual inspection is successful, carry out the function test.

2.2 Functional check of Stimuplex® HNS 12

Switch on the nerve stimulator. Target stimulation current = 0.00 mA, LED is not flashing, and no sound is audible. Battery symbol may not be flashing (battery voltage > 7 V).

- Connect electrode cable to the front of Stimuplex® HNS 12 (to the middle 4-polar plug). The plug connector configuration prevents wrong polarity connection. – Leave the circuit open.

- Use the **mA** function key to set the current range to 5.00 mA – Appears in display.

- Use the **ms** function key to set the stimulus duration to 0.30 ms – Appears in display.

- Use the **Hz** function key to set stimulation frequency to 1 Hz – Appears in display.

- Using the control knob, slowly increase the target stimulation current from 0.10 mA to 5.00 mA.

Throughout the entire procedure, warning display must read "Patient current lower than your setting" and patient current = "0.00 mA". The LED flashes red in a 1-Hz rhythm and the warning signal is audible in a 1-Hz rhythm.

- Close the circuit using the 10 kΩ test resistor supplied as an accessory. All warnings (display, LED, sound) must disappear. The display reads 10 kΩ ± - tolerance. If the warnings do not disappear, briefly connect the electrode cable to the contacts at the ends of the cable in order to rule out that test resistor is defective.

- Using the digital control knob, slowly reduce the target stimulation current from 5.00 mA to 0.02 mA. Throughout the entire procedure, the warning display must not read "Patient current lower than your setting", and the LED must be flashing green in a 1-Hz rhythm (if applicable yellow for target stimulation current < threshold current if option is activated).

In the event that the nerve stimulator does not behave as described, its use must be discontinued. The nerve stimulator and the electrode cable must be technically inspected.

Switch off the nerve stimulator so that any configured settings (from the medical team) are available when the device is switched back on.

These tests may be performed by qualified staff only and in accordance with the following test instructions (Section 6, para. 4 MPBetreibV). An equipment logbook of the technical safety checks must be kept (see appendix) and filed for the next safety inspection (Section 6, para. 3 MPBetreibV).

The following measuring and testing equipment is required:

Oscilloscope (storage oscillograph) for checking the output signal
Settings:
- Time base = 20 µs/div (500 ms/div) for stimulation frequency measurement
- Resolution = 500 mV, 1 V, 2 V, 10 V/div (full screen)
- Mode = High resolution is recommended for maximum accuracy (HiRes) or sample
- Trigger = falling slope, e.g. 30 %

Ohmmeter for checking test resistance
Test resistor 10 kΩ +/- 1%
9 V battery alkaline, battery voltage > 7 V.

3.1 Visual inspection of Stimuplex® HNS 12 and accessories

See Section 2.1. – Enter results in equipment logbook.

3.2 Functional check of Stimuplex® HNS 12

See Section 2.2. – Enter results in equipment logbook.

3.3 Checking the operating controls and monitoring equipment

- Check **instant set keys** (keypad)

mA key: Press the mA key repeatedly. In the display, the value is highlighted by a border for approx. 3 seconds. Only a value highlighted by a border can be changed by repeatedly pressing the key. Adjustable current range settings are 1.00 mA or 5.00 mA.

ms key: Press the ms key repeatedly. In the display, the value is highlighted by a border for approx. 3 seconds (see above). Adjustable settings are 0.10 ms, 0.30 ms, 1.00 ms stimulus duration (0.05 ms and 0.50 ms, if applicable).

Hz key: Press Hz key repeatedly. In the display, the value is highlighted by a border for approx. 3 seconds (see above).
Adjustable stimulation frequency settings are 1 Hz or 2 Hz.

MENU and ON/OFF keys:
When the stimulation screen is displayed, press I▶ arrow key → Main Menu is displayed.
Use ▼ to select "Setup" menu.
Press ▶ key. "Setup" menu is displayed.
Press ◀ key. Main menu reappears in the display.
Press **ON/OFF key** briefly. The stimulation screen reappears.

- Check digital **control knob**

In the stimulation screen turn control knob clockwise; this increases the target stimulation current; turn knob counter clockwise to reduce target stimulation current.

- **LCD** display: Readability check. If necessary, increase contrast by selecting Contrast menu.

Using the digital control knob, set target stimulation current = 5.00 mA.

- Check **LED** display with open circuit – LED lights up red.
- Check **LED** display with closed circuit – LED lights up green.

- Check **Sound** with open and closed circuit. If necessary, increase volume by selecting Volume menu.

Enter results in equipment logbook.

3.4 Checking the accessories

- Measure **10 kΩ ± 1 % test resistance** with the ohmmeter. Enter results in equipment logbook.

- Check **electrode cable** as described in Section 2.2. Enter results in equipment logbook.

If available:

- Connect **Stimuplex® Remote Control** to front of Stimuplex® HNS 12 (3-polar plug on left). The plug connector configuration prevents any wrong polarity connection.

- Use the remote control buttons to increase target stimulation current and reset to 0.00. Enter results in equipment logbook.

- Connect **Stimuplex® Pen** to electrode cable. Increase target stimulation current. The warning **"Patient current lower than your setting"** appears in the display. Then close the circuit with the test resistor. The warnings (display, LED, sound) must disappear. Enter results in equipment logbook.

3.5 Checking stimulation signal

To prevent disturbances, perform all tests only when the 9-volt battery is installed.

Connect the electrode cable using the **10 kΩ +/- 1% test resistor** – connect the oscillograph with GND clip on the red clamp parallel to test resistor.

Set stimulus duration = **0.10 ms** – target stimulation current = **1.00 mA.**
- Pulse form rectangular, negative.
- Measure stimulus duration – Enter results in equipment logbook.

Set stimulation frequency = **2 Hz** – target stimulation current = **1.00 mA.**
- Measure stimulation frequency – Enter results in equipment logbook.

Set stimulus duration = **0.10 ms** – target stimulation current = **0.30 mA.**
- Measure actual stimulation current – Enter results in equipment logbook.

Set stimulus duration = **0.10 ms** – target stimulation current = **0.50 mA.**
- Measure actual stimulation current – Enter results in equipment logbook.

Set stimulus duration = **0.10 ms** – target stimulation current = **1.00 mA.**
- Measure actual stimulation current – Enter results in equipment logbook.

Stimulus duration = **0.10 ms** – current range = **5.00 mA.** Using the control knob, set target stimulation current = **5.00 mA.**

- Measure actual stimulation current – Enter results in equipment logbook.

- Check impedance display with 10 kΩ test resistor. Enter results in equipment logbook.

If faults are detected, return the device – including accessories – to the manufacturer for repair.

A faulty electrode cable can be easily replaced on-site with a new one. The polarized connector prevents any wrong connection of electrode cable.

– **B. BRAUN** Code number for replacement electrode cable: **4892070**

Electrical and electronic equipment may only be repaired by the manufacturer or by an organization expressly authorized by the manufacturer.
Unauthorized persons opening or attempting to repair Stimuplex® HNS 12 can create a dangerous situation and will cause all warranty claims to be null and void.

Any order for repairs must be accompanied by a detailed description of the fault.

Example:

Type of device: Nerve Stimulator Stimuplex® HNS 12

Device No: _____

Last battery replacement: _____

Electrode cable checked: Passed ☐ Failed ☐

Description of the faults: _____

_____

_____

_____

_____

_____

_____

Contact persons (Name/Telephone): _____

_____

Your return address: _____

_____

Please send repairs from all EU countries to:
Stockert GmbH
Bötzinger Straße 72
79111 Freiburg
Deutschland

Please send repairs from all other countries to:
B. Braun Melsungen AG
LO-WF-DE08P
Attn.: Mr. Grützmacher
34209 Melsungen
Deutschland

For further request, please contact:
B. Braun Melsungen AG
Ms. Kranz
Pfieffewiesen
34212 Melsungen
Deutschland
e-mail: anja.kranz@bbraun.com
Telephon (0 56 61) 71-12 84
Telefax (0 56 61) 75-12 84

Test equipment logbook Stimuplex® HNS 12 **Serial No.** _____

Test equipment for the test:

Measuring device	Type	Calibrated	Next calibration
Ohmmeter			
Oszilloscope			

Visual inspection

Operating elements	Passed	Failed
Housing	☐	☐
Labels	☐	☐
Keypad (instant set keys)	☐	☐
LC Display	☐	☐
Control knob	☐	☐
Plugs	☐	☐
Electrode cable	☐	☐
Test resistor	☐	☐
Stimuplex® Remote Control if available	☐	☐
Stimuplex® Pen if available	☐	☐

Functional check **Passed** ☐ **Failed** ☐

Operational and monitoring elements check

Operational and monitoring elements	Passed	Failed
Keys	☐	☐
Control knob	☐	☐
LC Display	☐	☐
LED display green (yellow, if applicable), red	☐	☐
Sound, warning signal	☐	☐

Accessories functional check

Accessories	Passed	Failed
Test resistor 10 kΩ +/- 1 %	☐	☐
Electrode cable	☐	☐
Stimuplex® Remote Control, if available	☐	☐
Stimuplex® Pen, if available	☐	☐

Stimulation signal check

Test	Stimuplex® HNS 12 Setting	Tolerance	Passed	Failed
Pulseform	0.10 ms, 1.00 mA	Square, negative	☐	☐
Stimulation duration	0.10 ms, 1.00 mA	0.098 ms – 0.102 ms	☐	☐
Stimulation frequency	2 Hz, 1.00 mA	1.98 Hz – 2.02 Hz	☐	☐
Stimulation current	0.10 ms, 0.30 mA, 10 kΩ +/- 1%	0.26 mA – 0.34 mA	☐	☐
Stimulation current	0.10 ms, 0.50 mA, 10 kΩ +/- 1%	0.46 mA – 0.54 mA	☐	☐
Stimulation current	0.10 ms, 1.00 mA, 10 kΩ +/- 1%	0.96 mA – 1.04 mA	☐	☐
Stimulation current	0.10 ms, 5.00 mA, 10 kΩ +/- 1%	4.96 mA – 5.04 mA	☐	☐
Impedance	0.10 ms, 5.00 mA, 10 kΩ +/- 1%	9 kΩ – 11 kΩ	☐	☐

Remarks: _____

_____

_____

_____

_____

_____

Technical inspector: **Date:** **Signature:**

_____ _____ _____